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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,493	05/05/2006	Laurent Desire	67987.000002	7885

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
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WASHINGTON, DC 20006-1109

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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11/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,493	Applicant(s) DESIRE, LAURENT	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claim 12-14 and 19 have been cancelled and claims 20-37 added as requested in the amendment filed on August 26, 2009. Following the amendment, claims 20-37 are pending in the instant application.

Claims 20-37 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on August 26, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below. New grounds of rejection are set forth below as well.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **New** claims 20-37, **as currently presented**, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex*

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parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 20 and 29 recite the broad recitation "a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 [or 2]", and the claim also recites "an epitope created by the junction of exon 3 and exon 5" which is the narrower statement of the range/limitation. Since the specificity and novelty of an antibody is defined by the structure of its binding epitope, and in the instant case this structure is indefinite, claims 20 and 29 are vague and ambiguous as presented. Claims 21-28 and 30-37 are indefinite as being dependent from indefinite claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **New claims 20-37, as currently presented**, are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,420,534, Gurney et al, ('534 patent) for reasons of record as

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applied to claims 12-14 and 19 in section 17 of Paper mailed on March 28, 2008, section 6 of Paper mailed on November 07, 2008 and section 6 of Paper mailed on April 17, 2009.

Applicant argues that the new claims now recite antibodies that “bind an epitope created by the junction of exon 3 and exon 5, i.e., do not bind an epitope including exon 4. The claims also require that the antibodies, fragments or derivatives thereof selectively bind BACE455 polypeptides, i.e., specifically bind BACE455 polypeptides, but do not specifically bind non-BACE 455 polypeptides”, p. 4 of the Response. Applicant’s argument has been fully considered but is not persuasive for the following reasons.

As an initial matter, the claims, as currently presented, are vague and ambiguous for failure to clearly identify the specificity of the binding epitope, see reasons of record in section 5 of the instant office action. Second, limitation “selectively binds” by broadest reasonable interpretation is construed as binds to any epitope within the structure recited in the claims – SEQ ID NO: 5 (or 2). Note that the peptide of SEQ ID NO: 5 is an eight amino acids long fragment of the polypeptide of SEQ ID NO: 2 and since the ‘534 Patent teaches antibodies that bind to SEQ ID NO: 6, the amino acid sequence with 99.2% sequence similarity to the instant SEQ ID NO: 2, the claims 20-37 are fully anticipated.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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9. **New** claims 20-37 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,583,275, ('275 Patent) for reasons of record in section 8 of Paper mailed on April 17, 2009.

Applicant argues at p. 5 of the Response that “[c]laim 20, for example, is directed to antibodies, fragments or derivatives thereof that selectively bind polypeptides comprising the amino acid sequence of SEQ ID NO: 5 (EIARIIGG) [and] [t]he ‘275 patent does not teach such antibodies”. Applicant’s argument has been given careful consideration but is not persuasive because the art clearly teaches that minimal antigenic epitope is a stretch of five amino acids (Redehasse et al., 1989, Nature, Vol. 337 (6208), pp. 651-3) and the ‘275 patent teaches a polypeptide comprising six common amino acids with the instant peptide of SEQ ID NO: 5 (IARIIG), teaches antibodies that bind to that peptide, thus fully anticipating the instant invention.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.

November 17, 2009

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/Olga N. Chernyshev/

Primary Examiner, Art Unit 1649